APR 1 9 2002

APPENDIX A **510(K) SUMMARY**

FETAL ASSIST

Submitter's Name: Ms Audrey A. Witko,
Vice President - Administration, Compliance & Clinical Affairs
Huntleigh Healthcare,
40 Christopher Way
Eatontown, NJ 07724-3327
USA
Telephone N°: (800) 223 1218 ext. 127
e-mail: audreyw@huntleighhealth.com

Name of Device: **FETAL ASSIST**

Manufactured by: Huntleigh Diagnostics Ltd
35, Portmanmoor Road,
Cardiff
South Glamorgan CF24 5HN
Wales, U.K.

Contact Person at Manufacturing Facility:
B.J.Colleypriest
Telephone N°: 011 2920 485885
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e-mail bryn.colleypriest@huntleigh-diagnostics.co.uk

Date Special 510(k) prepared: **25 January 2002**

Classification Name Perinatal Monitoring System 2740
~~Fetal Ultrasonic Monit~~or and Accessories (21 CFR § 884.~~2660~~)
Home Uterine Activity Monitors (21 CFR § 884.2730)

Predicate Devices
FETAL ASSIST (K002548)

Device Description

The FETAL ASSIST is a modular product that provides a portable antepartum fetal monitor that produces fetal cardiotocographs (CTGs).
CTG traces are displayed in real time on the Liquid Crystal Display (LCD) which is integral to the Host Unit. The CTG's are stored within the integral memory of the Host Unit and can be reviewed or downloaded to an external printer and/or central location.
Power to energize the system is supplied by a stand-alone rechargeable battery pack. Alternatively, the Assist can be powered from the AC-powered supply via a power adapter.

Intended use

The FETAL ASSIST is suitable for use in all conventional antepartum fetal monitoring applications from a gestation age of approximately 26 weeks. It is particularly intended for use in the following specific areas:-

Antenatal monitoring in the hospital, doctors office, health clinic, home or community.
External Labour monitoring.
Home Uterine Activity Monitoring (HUAM) and/or Non Stress Testing

NB: Before being used in domiciliary HUAM and/or Non Stress Testing applications the mother would be instructed in the use of the equipment.

The FETAL ASSIST is a prescription device..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 9 2002

Ms. Audrey Witko
Vice President, Administration,
Compliance & Clinical Affairs
Huntleigh Healthcare, Inc.
40 Christopher Way
EATONTOWN NJ 07724-1218

Re: K020390
Trade/Device Name: Fetal Assist for Home Uterine Monitoring
Regulation Number: 21 CFR 884.2730
Regulation Name: Home uterine activity monitor
Regulatory Class: II
Product Code: 85 LQK
Trade/Device Name: Fetal Assist for Home
Non-Stress Test Monitoring
Regulatory Number: 21 CFR 884.2740
Regulatory Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 MOH
Dated: January 24, 2002
Received: February 6, 2002

Dear Ms. Witko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Huntleigh
DIAGNOSTICS

Huntleigh Diagnostics Ltd
A Huntleigh Technology PLC Company

APPENDIX E INDICATIONS FOR USE

510(k) Number K020390

Device Name: **FETAL ASSIST**

Indications for Use

The FETAL ASSIST is suitable for use in all conventional antepartum fetal monitoring applications from a gestation age of approximately 26 weeks. It is particularly intended for use in the following specific areas: -

- Antenatal monitoring in the hospital, doctors office, health clinic, home or community.
- External Labour monitoring.
- Waterbirth monitoring using optional waterproof transducers.
- Home Uterine Activity Monitoring (HUAM) in conjunction with standard high-risk care, for the daily at-home measurement of uterine activity for women with a history of preterm birth.
- Domiciliary Non Stress Testing applications.

The FETAL ASSIST is a prescription device.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over the counter use _____
(Per 21 CFR 801.109)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020390